This document is an English-translated version of an attachment of a notification for Revision of PRECAUTIONS issued by the Ministry of Health, Labour and Welfare.
This English version is intended to be a reference material to provide convenience for users.
In the event of inconsistency between the Japanese original and this English translation, the former shall prevail.

Revision of PRECAUTIONS

Ceritinib

March 17, 2026

Therapeutic category

Other antitumor agents

Non-proprietary name

Ceritinib

Safety measure

PRECAUTIONS should be revised.

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Revised language is underlined.

Current	Revision
2. CONTRAINDICATIONS (This drug is contraindicated to the following patients.) Patients receiving the following drugs: Venetoclax (relapsed or refractory chronic lymphocytic leukaemia (including small lymphocytic lymphoma) and relapsed or refractory mantle cell lymphoma during the dose escalation phase)	2. CONTRAINDICATIONS (This drug is contraindicated to the following patients.) Patients receiving the following drugs: Venetoclax (relapsed or refractory chronic lymphocytic leukaemia (including small lymphocytic lymphoma) and relapsed or refractory mantle cell lymphoma during the dose escalation phase), anamorelin hydrochloride, ivabradine hydrochloride, quinidine sulfate hydrate, ticagrelor, azelnidipine, olmesartan medoxomil/azelnidipine, eplerenone, ergotamine tartrate/anhydrous caffeine/isopropylantipyrine, simvastatin, tadalafil (Adcirca), macitentan/tadalafil, finerenone, lomitapide mesilate, suvorexant, triazolam, blonanserin, lurasidone hydrochloride, vardenafil hydrochloride hydrate, methylergometrine maleate, ibrutinib
(N/A)	Patients with hepatic or renal impairment receiving colchicine
9. PRECAUTIONS CONCERNING PATIENTS WITH SPECIFIC BACKGROUNDS (N/A)	9. PRECAUTIONS CONCERNING PATIENTS WITH SPECIFIC BACKGROUNDS 9.2 Patients with Renal Impairment Patients with renal impairment receiving colchicine This drug should not be administered. The blood concentration of colchicine may increase.

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9.3 Patients with Hepatic Impairment (N/A) Patients with severe hepatic impairment	9.3 Patients with Hepatic Impairment <u>Patients with hepatic impairment receiving colchicine</u> <u>This drug should not be administered. The blood concentration of colchicine may increase.</u> Patients with severe hepatic impairment <u>(excluding patients receiving colchicine)</u>

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<table>
<tr>
<td>10. INTERACTIONS
10.1 Contraindications for Co-administration (Do not co-administer with the following.)
(N/A)</td>
<td>10. INTERACTIONS
10.1 Contraindications for Co-administration (Do not co-administer with the following.)
<table>
<tr><th>Drugs</th><th>Signs, symptoms, and treatment</th><th>Mechanism/risk factors</th></tr>
<tr><td>Anamorelin hydrochloride
Ivabradine hydrochloride
Quinidine sulfate hydrate
Ticagrelor
Azelnidipine
Olmesartan medoxomil/azelnidipine
Eplerenone
Ergotamine tartrate/anhydrous caffeine/isopropylantipyrine
Simvastatin
Tadalafil (Adcirca)
Macitentan/tadalafil
Finerenone
Lomitapide mesilate
Suvorexant
Triazolam
Blonanserin
Lurasidone hydrochloride
Vardenafil hydrochloride hydrate
Methylergometrine maleate
Lonafarnib
Ibrutinib</td><td>Adverse reactions to these drugs may be enhanced.</td><td>Strong CYP3A inhibition by ceritinib may suppress the metabolism of these drugs, leading to an increase in the blood concentration of these drugs.</td></tr>
</table>
</td>
</tr>
</table>

N/A: Not Applicable. No corresponding language is included in the current PRECAUTIONS.